



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,822	09/07/2004	Michael Ausborn	DV/4-32408A	8924

1095 7590 12/20/2007
NOVARTIS
CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER

YEBASSA, DESTA LETTA

ART UNIT	PAPER NUMBER
----------	--------------

1615

MAIL DATE	DELIVERY MODE
-----------	---------------

12/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/506,822

Applicant(s)

AUSBORN ET AL.

Examiner

Desta L. Yebassa

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 22-41 is/are pending in the application.
4a) Of the above claim(s) 22-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 39-41 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 22-34 and 38, drawn to a process for the preparation of microparticles containing a pharmaceutically active ingredient.

Group II, claims 22 and 35-37, drawn to a process for the preparation of microparticles containing a peptide, polypeptide or protein.

Group III, claims 39-41, drawn to microparticles.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

A special technical feature is considered to be a contribution over the prior art.

Alpar et al disclose microparticles comprising a biologically active agent, active substance (phospholipids), polymeric materials capable of forming a microsphere, (abstract). Alpar et al also disclose biodegradable polymer such as polycarbonates and the like and water soluble polymers such as polyvinyl alcohol that reads on group III (abstract, page 5, line 25). In addition, the employment of gear pumps for processing

fluids is well known in the art see for example US 5,593,687 which indicates that step e) of claim 23 does not constitute a special technical feature..

During a telephone conversation with Attorney Kung, John on 11/13/07 a provisional election was made without traverse to prosecute the invention of Group I, claims, 39-41. Affirmation of this election must be made by applicant in replying to this Office action. Claims 22-38 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

DETAILED ACTION

Acknowledgment is made for the information disclosure statement (IDS) filed 06/24/2005 and foreign priority filed on 09/07/2004.

Receipt also acknowledged of the oath or declaration filed on 09/07/2004.

Claims 22-41 are pending.

Claims 39-41 rejected.

Claims 1-21 are canceled

No claims are allowed.

Information Disclosure Statement

The listing of references in the Search Report of 06/24/2005 is not considered to be an information disclosure statement (IDS) complying with 37 CFR 1.98. 37 CFR 1.98(a)(2) requires a legible copy of: (1) each foreign patent; (2) each publication or that portion which caused it to be listed; (3) for each cited pending U.S. application, the application specification including claims, and any drawing of the application, or that portion of the application which caused it to be listed including any claims directed to that portion, unless the cited pending U.S. application is stored in the Image File Wrapper (IFW) system; and (4) all other information, or that portion which caused it to be listed. In addition, each IDS must include a list of all patents, publications, applications, or other information submitted for consideration by the Office (see 37 CFR 1.98(a)(1) and (b)), and MPEP § 609.04(a), subsection I. states, "the list ... must be submitted on a separate paper." Therefore, the references cited in the Search Report have not been considered. Applicant is advised that the date of submission of any item of information or any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the IDS, including all "statement" requirements of 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-41 are rejected under 35 U.S.C. 102(b) as being anticipated by Alpar et al (WO 00/56282).

Alpar et al disclose microparticles comprises biologically active agent, active substance (phospholipids) and polymeric materials capable of forming microsphere (abstract). Alpar et al also disclose biodegradable polymer such as polycarbonates and the like (page 5, lines 1-70 as listed in specification (page 3, paragraph 4) and water soluble polymers such as polyvinyl alcohol (page 5, line 25) as listed in specification (page 4, paragraph 2). The microparticles having an average diameter size from about 0.1 microns to about 10 microns (page 5, lines 28-29). The active ingredient comprises from about 0.1 % to 10 % active agent (page 9, lines 6-7). Since the microparticles diameter size and active agent percentage taught by Alpar et al overlaps the microparticles diameter size and active agent percentage claimed invention, Alpar et al clearly anticipates claim 40-41. See MPEP § 2131.03 [R-5] II. Anticipation of Ranges

II. PRIOR ART WHICH TEACHES A RANGE * OVERLAPPING* OR
TOUCHING THE CLAIMED RANGE ANTICIPATES IF THE PRIOR ART
RANGE DISCLOSES THE CLAIMED RANGE WITH "SUFFICIENT
SPECIFICITY"

Therefore, Alpar et al clearly anticipates claims 39-41.


Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Desta L. Yebassa whose telephone number is 571-272-8511. The examiner can normally be reached on Monday to Friday 8.00 am –6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Desta L. Yebassa, Ph.D.
Patent Examiner
Art Unit 1615


MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600